TRAC SCIENCE POLICY AREA #3: EXPOSURE ASSESSMENT - "NO RESIDUES DETECTED"

11/30/98

Following are summaries of the key points in three draft science policy papers announced in the Federal Register for public comment.

A

Threshold of Regulation Policy

--Concerns food uses for which data at the farm gate show no detected (ND) residues with a limit of quantitation (LOQ) at 0.01 ppm or less.

--If NDs for a use are shown to be less than 1/10 the limit of quantitation (LOQ), residues are deemed to be "essentially zero" and no tolerance would be required.

--If NDs for a use are shown to have "essentially zero" risk (i.e., risk is 1/1000 of an acceptable level of risk), then no tolerance would be required. The values of the NDs are determined as described for paper B (see next box).

--If neither criterion is met, then a finite tolerance would be established at the LOQ, assuming the use meets FQPA safety standards.

B

Assigning Values to Nondetected/ Nonquantified Pesticide Residues in Dietary Exposure Assessments

--Concerns each food use for which data show some detectable and some ND residues.

--In conducting exposure and risk assessments, EPA would assign a value to NDs for each treated crop as follows:

1. If an LOD exists, NDs = ½ LOD
2. If an LOQ exists, NDs = ½ LOQ
3. If only an LLMV exists, NDs = LOQ
4. If nonquantifiable residues are found, NDs = ½ LOQ.

Key

LOD = Limit of Detection
LOQ = Limit of Quantitation
LLMV = Lower Limit of Method Validation

C

Statistical Method for Using Nondetected Residues in Dietary Exposure Assessments

--As an alternative to using ½ LOD for NDs, statistical methods (e.g., "Cohen's Method") could be used to estimate the distribution of ND values for treated food.

--The criteria for using Cohen's method are:

1. The NDs comprise less than half of the data set.

2. The values for the detected residues are normally or lognormally distributed.